K131617

510(k) Summary

1. Submitter/510(k) Holder

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2. Device Name

Trade Name:	Colonglide® Lubricant
Common Name:	Patient lubricant
Classification Name:	Lubricant, Patient, 21 CFR 880.6375
Device Class:	Class I
Classification Panel:	General Hospital Panel
Product Code:	KMJ

3. Predicate Devices

PDI® Sterile Lubricating Jelly (Nice-Pack Products Inc., K974768)

Aquagel® Lubricating Jelly (DePuy Healthcare, K951431)

4. Device Description

Colonglide® Lubricant is a clear, colorless, non-sterile, odorless, water-based patient lubricant. The subject device is packaged for individual use in a 250 mL round plastic bottle sealed with a screw cap with a foil induction innerseal liner.

5. Indication for Use

Colonglide® Lubricant is intended for medical purposes for use to lubricate a body orifice of a patient in order to facilitate the entry of a diagnostic or therapeutic medical device (such as an endoscope). This device is intended for use on order of a physician.

6. Technological Characteristics

A tabular summary comparing the technological characteristics of Colonglide® Lubricant to the predicate devices is presented in Table 5-1 below.

7. Non-Clinical Testing

Performance testing conducted on Colonglide® Lubricant meets all the pre-determined acceptance criteria for appearance, pH, viscosity, specific gravity, preservatives, and microbial limits to support the safety and effectiveness of the finished device.

A comparative pH test was performed on the device formulations for Colonglide® Lubricant and the predicate devices; the formulations were determined to be equivalent. The pH results (average) reported for Colonglide® Lubricant and the predicate devices are provided in Table 5-1.

Physicochemical testing conducted on the device plastic bottle met all test method acceptance criteria in accordance with current USP requirements for Containers-Plastics <661>.

The current shelf-life is 6-months with testing ongoing to support a 24-month shelf-life.

Biocompatibility testing was conducted on the finished device according to ISO 10993-1:2009.

The predicate device, PDI® Sterile Lubricating Jelly, was used as a control article in the biocompatibility safety tests evaluating the sensitization and irritation of Colonglide® Lubricant. The negative test results reported for both sensitization and irritation confirm that Colonglide® Lubricant is as safe as the predicate device, PDI® Sterile Lubricating Jelly.

8. Clinical Testing

An open-label pilot study was conducted to evaluate the use of Colonglide® Lubricant in 30 patients undergoing a routine screening colonoscopy.

The effectiveness of Colonglide® Lubricant to facilitate the performance of a colonoscopy was evaluated by three study investigators enrolling 10 patients each into the study. The effectiveness of Colonglide® Lubricant to facilitate the performance of a colonoscopy was reported for 57% of the total study population. Each study investigator reported that Colonglide® Lubricant facilitated the colonoscopy in at least 50% of the patients.

Most patients (24/30) required either minimal or moderate amount of applied external pressure during their procedure. Successful intubation to the cecum was reported in 100% of the study patients. The median time needed to reach the cecum was 7 minutes.

No adverse effects related to the use of Colonglide® Lubricant were reported by the study investigators. Also, there were no adverse effects or gastrointestinal problems reported by any of the study subjects contacted within 72 hours of the completed procedure.

In a published study by Brocchi, et al. (2005), a prospective, randomized, controlled study was conducted to determine whether the performance of a colonoscopy could be facilitated by

instillation of corn oil through the biopsy channel of the colonoscope during the procedure when compared to a standard lubricating method.

A total of 346 subjects underwent a colonoscopy with a standard lubricating method (using water-soluble KY jelly; group A) or with the standard method plus seed oil (corn oil) instillations through the biopsy channel (group B).

Successful intubation to the cecum was significantly more frequent ($P < 0.005$) in the corn oil lubrication group (group B, 159/168) than in the control group (group A, 145/170), and less time was needed for the corn oil group ($P < 0.001$). No significant differences were found with regard to time for examination at withdrawal and detection rates for colorectal diseases. Level of pain and degree of difficulty during colonoscopy were significantly lower in the corn oil group ($P < 0.001$). In the crossover examinations done in subjects in whom total colonoscopy was not achieved, no statistical difference was found between the two groups.

No adverse effects were reported for any of the study subjects in either the corn oil (group B) or the control group (group A). No damage to the instrument (i.e., colonoscope) was observed in the study.

In another published study by Brocchi, et al. (2008), a prospective, randomized, controlled study was conducted in 510 eligible subjects who underwent a colonoscopy and were randomly assigned into three groups: a standard lubricating method (water-soluble KY jelly: group A, 170 subjects) was adopted in a control group, whereas the standard method plus instillation into the colon of corn seed oil (group B, 170 subjects) or warm water (group C, 170 subjects) was employed in the other groups.

In group A, 6/170 subjects were excluded from the study (total colonoscopy judged "impossible") because of obstructive cancers (5 subjects) or impassable strictures (1 subject). Additionally; 4/170 subjects in group B and 7/170 in group C were excluded because of obstructive cancers (2 subjects in group B and 4 subjects in group C) and strictures (2 subjects in group B and 3 subjects in group C). Impassable strictures were always due to diverticular disease and adherences at the level of the sigmoid colon.

Successful intubation to the cecum was reported in 138/164 subjects (84.1%) in group A, 155/166 subjects (93.4%) in group B, and 156/163 subjects (95.7%) in group C. The differences between groups A and B and between groups A and C were statistically significant ($P < 0.01$ and $P < 0.001$, respectively), whereas between groups B and C were not significant ($P = 0.864$).

The median time needed to reach the cecum was significantly ($P < 0.001$) shorter in groups B (9.2 min) and C (9.1 min) when compared with group A (13.2 min). However, there was no significant difference in the time to reach the cecum between groups B and C. The time of withdrawal was similar in all three groups, with no significant difference.

Pain and technical difficulties experienced during the procedure were significantly lower in groups B and C than in group A ($P < 0.001$); no difference was found between groups B and C.

No adverse effects were noted in any of the subjects participating in the study. No damage to the instrument (i.e., colonoscope) was observed in the study. Thus, the use of patient lubricants in colonoscopy did not present any patient safety concerns in the study.

9. Conclusions Drawn from Non-Clinical and Clinical Tests

Colonglide® Lubricant has the same intended use and similar technological characteristics as the predicate devices. Colonglide® Lubricant and the predicate devices are all water-soluble lubricants for medical and/or professional use.

The formulation pHs for Colonglide® Lubricant and the predicates devices were evaluated and found to be equivalent. Biocompatibility testing of Colonglide® Lubricant showed it to be as safe as PDI® Sterile Lubricating Jelly in both sensitization and irritation assays.

The clinical investigation of Colonglide® Lubricant to facilitate the performance of a colonoscopy demonstrated: (1) increased patient safety; (2) decreased use of external pressure maneuvers; and (3) increased efficiency in performing the procedure.

In clinical studies performed by Brocchi et al., the use of a standard lubricating method along with the instillation of either corn oil or warm water through the biopsy channel of a colonoscope demonstrated improved performance for facilitating the procedure when compared to the use of a standard lubricating method. No adverse effects were noted in any of the subjects participating in the studies.

The similarity of the technological characteristics and performance data from comparative and biocompatibility testing confirm that Colonglide® Lubricant is substantially equivalent to the predicate devices.

Table 5-1. Side-by-Side Comparison of Colonglide® Lubricant with Predicate Devices

	Colonglide® Lubricant	PDI® Sterile Lubricating Jelly (Nice-Pack Products Inc.)	Aquagel® Lubricating Jelly (DePuy Healthcare)
Regulatory Status	Proposed	K974768	K951431
Product Code	KMJ	KMJ	KMJ
Intended Use	Colonglide® Lubricant is intended for medical purposes for use to lubricate a body orifice of a patient in order to facilitate the entry of a diagnostic or therapeutic medical device (such as an endoscope). This device is intended for use on order of a physician.	PDI® Sterile Lubricating Jelly is intended for use to lubricate a body orifice of a patient in order to facilitate the entry of a diagnostic or therapeutic medical device (such as a catheter, enema tip, or endoscope). The device is intended for use on order of a physician.	Aquagel® is intended for use in gynecological, digital and instrument examinations and general hospital procedures.
Contains Lubrication Base/Solvent	Yes	Yes	Yes
Contains pH adjuster or buffer	Yes	Yes	Yes
Contains thickening agent	Yes	Yes	Yes
Contains preservatives	Yes	Yes	Yes
Contains sequestering agents	None	None	Yes
Physical state	Liquid, gel	Liquid, paste/gel	Gel
Clear Appearance	Yes	Yes	Yes
Odorless	Yes	Yes	Yes
pH*	5.88	5.98	6.78
Water soluble	Yes	Yes	Yes
Specific Gravity	1.042	1.03	1.045
Biocompatible	Yes	Yes, sensitization and irritation**	Yes
Size and packaging	250 mL plastic bottle	2.7 g and 5.0 g packet	142 g plastic tube, half gallon (1.9 L) plastic jug with pump
Shelf Life	2 years	Manufacturer information is not available	2 years
Sterile	No	Yes, gamma irradiation	No

* Comparative pH testing of Colonglide® Lubricant with predicate devices.

** Comparative biocompatibility studies were conducted to evaluate the sensitivity and irritation of Colonglide® Lubricant and the predicate PDI® Sterile Lubricating Jelly.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 3, 2013

Pediatric Pharmaceuticals, Incorporated
C/O Mr. Robert M. Harris
Vice President
Harris FRC Corporation
2137 Route 35
HOLMDEL NJ 07733

Re: K131617
Trade/Device Name: Colonglide Lubricant
Regulation Number: 21 CFR 880.6375
Regulation Name: Patient Lubricant
Regulatory Class: I
Product Code: KMJ
Dated: August 15, 2013
Received: August 19, 2013

Dear Mr. Harris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
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Office of Device Evaluation
Center for Devices and
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Enclosure

Indications for Use

510(k) Number (if known): K131617

Device Name: Colonglide® Lubricant

Indications for Use:

The Colonglide® Lubricant is indicated for medical purposes for use to lubricate a body orifice of a patient in order to facilitate the entry of a diagnostic or therapeutic medical device (such as an endoscope). This device is intended for use on order of a physician.

Prescription Use _x_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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